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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,768	04/02/2004	Hermann Oppermann	003443-0020-102	3980
1473	7590	02/18/2010		
ROPER & GRAY LLP PATENT DOCKETING 39/361 1211 AVENUE OF THE AMERICAS NEW YORK, NY 10036-8704			EXAMINER LI, RUXIANG	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 02/18/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/816,768

**Applicant(s)**

OPPERMANN ET AL.

**Examiner**

RUIXIANG LI

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### **Status of Application, Amendments, and/or Claims**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/22/2010 has been entered.

Claims 1-19 are pending. Claims 6-9 are currently under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### **Claim Rejections under 35 U.S.C. §102(e)**

(i). The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(ii). Claims 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Nimni et al. (U.S. Patent No. 6,352,972 B1, March 5, 2002; 102(e): June 3, 1997).

Nimni et al. teach a TGF- $\beta$  fusion protein comprising a human TGF- $\beta$ 1 active fragment (the C-terminal domain of TGF- $\beta$ 1) and a leader sequence (Example 1). The leader sequence may comprise a purification tag, proteinase-sensitive linker sites and a protein binding domain such that the leader sequence may contain all or some of the following elements: purification tag; proteinase site: ECM binding site: proteinase site: TGF- $\beta$  (columns 3-4). Table 1 (column 5) lists various TGF- $\beta$ 1 fusion proteins, such as a His-tagged C-terminal active fragment of TGF $\beta$ 1 (Table I, lines 2; Example 1). Nimni et al. teach that the refolded fusion protein under low concentrations of urea and DTT or a redox system used DTT in conjunction with glutathione had little or biological activity (Example 5, column 10, lines 44-57; column 11, lines 6-8).

Nimni et al. also teach a BMP fusion protein comprising a mature BMP protein (column 7, line 62) or an active portion of BMP proteins (a subset of the TGF $\beta$  family), such as OP-1, also called BMP-7 (column 2, line 22; column 3, lines 1-18). Nimni et al. further teach a fusion protein comprising a human OP-1 (BMP-7) active fragment (column 3, lines 37-48). Since the mature human OP-1 or the active portion of human OP-1 would necessarily comprises the subdomains recited in claim 6 and satisfy the structural requirement, the additional properties recited in claims 6-8 are inherent to the structure of the fusion protein.

Accordingly, the teachings of Nimni et al. meet the limitations of claims 6-8.

(iii). Response to Applicants' argument

Applicants argue that claims have been amended to recite a latent OP-1 fusion protein comprising specific OP-1 finger 1, finger 2 and heel subdomain sequences. Applicants argue that Nimni et al. do not teach fusion proteins comprising such OP-1 sequences.

Applicants' argument has been fully considered, but is not deemed to be persuasive because, as noted above,

Nimni et al. teach a BMP fusion protein comprising a mature BMP protein or an active portion of BMP proteins, such as OP-1. Nimni et al. also teach a fusion protein comprising a human OP-1 (BMP-7) active fragment. Since the mature human OP-1 or the active portion of human OP-1 would necessarily comprises the subdomains recited in claim 6 and satisfy the structural requirement, the teachings of Nimni et al. meet the limitations of claims 6-8.

**Conclusion**

No claims are allowed.

**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646  
February 10, 2010